UNITED STATES FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF THERAPEUTICS RESEARCH AND REVIEW
DIVISION OF CLINICAL TRIAL DESIGN AND ANALYSIS

Memo To: **The File, BLA Supplement # 97-0201**

Subject: **Summary of Basis for Approval**

Reviewer: Dina S. Stolman, M.D., Clinical Reviewer, General Medicine Branch DSStolman
Chair, Review Committee

Through: Marc Walton, M.D., Ph.D., Branch Chief, General Medicine MW 2/18/98

Karen Weiss, M.D, Director, Division of Clinical Trial Design & Analysis KW 2-21-98

Date: February 18, 1998

The sponsor seeks to add to the present package labelling

- A statement that the benefit seen on the primary endpoint of the EPIC trial extends to 3 years follow-up, and
- Additional *in vitro* data on the effects of Abciximab on the vitronectin receptor and inhibition of thrombin generation.

The BLA review team recommends approval of the proposed changes to the product labeling for Abciximab based on the items submitted in BLA # 97-0201. Modification of the wording has been proposed by the agency, and an agreement reached with the sponsor.

Please refer to section 10.0 of the attached Medical Officer's Review for a discussion of the evidence supporting each of these claims. Additional discussion is provided in the Pharmacology Review.